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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Badley et al.

Application No.: 09/554,956

Filed: 7/11/2000

Title: Improvements in or Relating to
Displacement Assays

Attorney Docket No.: IMIN.P-019

Group Art Unit: G Gabel

Examiner: 1641

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICIAL ACTION

Dear Sir:

This is in response to the Official Action mailed January 15, 2003 for the above-captioned application. Applicants request an extension of time sufficient to make this paper timely, and enclose the fee. The Commissioner is authorized to charge any additional fee or to credit any overpayment to Deposit Account No. 15-0610.

Reconsideration of the application is respectfully requested.

Claims 1-3, 5-16 and 22 are pending and under examination.

The Examiner rejected the claims under 35 USC § 112, second paragraph.

Applicants respectfully traverse this rejection.

The Examiner states that the phrase "a species capable of producing a detectable signal" in claim 1 is indefinite. She states that it is unclear what is encompassed by the term

I hereby certify that this paper and any attachments named herein are being deposited with the US Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on July 15, 2003.

Marina T. Larson
Marina T. Larson, PTO Reg. No. 32,038

July 15, 2003
Date of Signature

"species." Applicants submit that it is in fact clear from reading the claim and using the ordinary meaning of the terms, that the "species" is simply the thing that is formed when capture occurs. With respect to how the species produces a signal, this would be a description of how to practice the invention, which is, as here, appropriately set forth in the specification. For compliance with the definiteness requirements, the person skilled in the art would understand that the capture of the displaceable moiety leads to the formation of something (a species) that is detectable, and that this species is then detected in the following step of the method of claim 1. The Examiner also states that this phrase is not a positive limitation because of the use of the term "capable of". Again, Applicants respectfully disagree. The term refers to the structure by its function, because it is not required that the detectable signal be generated spontaneously upon capture. It is nevertheless a positive limitation because capture which results in a species which can be detected in a way which is distinguishable from other the uncaptured displaceable moiety, and the capture moiety, prior to capture of the displaceable moiety, is required by the claim.

The Examiner also states that it is unclear what the term "treating" means in claim 1. The term "treating" means simply doing something to the species formed upon capture so that the signal is generated. By way of non-limiting example, in the case where a fluorescent species or one which quenches pre-existing fluorescent properties is formed, the treatment might be provided via an excitation light source or an evanescent wave. Where the detectable signal is an electrochemical signal, the treatment may be application of a potential or a current.

For the foregoing reasons, Applicants submit that the claims comply with the requirements of 35 USC § 112, second paragraph. Should the rejection be maintained, Applicants note that the Examiner bears the burden of establishing "that one having ordinary skill in the art would not have been able to determine the scope of protection defined by the claim when read in light of the specification." *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (POBAI 1989). Merely stating that something is unclear or indefinite does not meet this standard. On the merits, the Examiner again rejected claims 1-3, 7-10 and 13-16 as anticipated by Schramm et al. (WO 91/05262). Claim 1, upon which all of the rejected claims depend, requires the generation and detection of a signal. However, as specified in the claim, "the detectable signal cannot be generated unless and until the displaceable moiety is captured on the second surface."

In the Response to Arguments on Page 8 of the outstanding Office Action (January 15, 2003), the Examiner asserts that this limitation is met because

the claimed invention at lines 9-16 specifically relies upon an interaction that takes place in the second surface in the presence of analyte, wherein the second surface bears a capture moiety upon which the displaceable moiety from the first surface is captured, thus causing the generation of a signal at the second surface.

Applicants are not sure what the Examiner is referring to when "the claimed invention at lines 9-16" is mentioned. It would seem that the Examiner is paraphrasing amended claim 1, leaving out limitations which have been argued to be important for distinguishing the reference, and then saying that all of the limitations the Examiner chooses to count are found in the reference. This is improper. The fact that a signal is generated at the second surface, which is all that is disclosed in Schramm, does not in any way require that the signal generating species be one which is formed by the capturing act and which is not capable of generating the same signal in the absence of capture. That, however, is what the claims of the present invention require, and the Examiner may not omit limitations from the claim in assessing patentability.

The Examiner also states that Schramm is encompassed in the embodiment set forth in the second full paragraph on Page 7 of the present application. This specific embodiment describes enzyme bound at the second surface, and an interaction with this enzyme to change its ability to convert substrate when the displaceable moiety is also bound at the bound surface. The Examiner has not pointed to any disclosure in Schramm which functions in this manner, and thus has failed to show that Schramm would anticipate an embodiment of this type. Indeed, in Schramm, the only disclosure of enzymes is as a signal-generating means that is conjugated to the analyte to serve as a displaceable moiety in the competitive binding reaction. This difference not only shows that Schramm does not disclose an embodiment as in the referenced paragraph on Page 7, it also highlights the fact that Schramm neither discloses nor suggests an assay in which capture of the displaceable reagent is required for the signal-generating function to be activated.

The Examiner also maintained the rejection of claims 1-3, 7-8, 11 and 14-16 as anticipated by Partin et al. US Patent No. 5,082,630. In order to be anticipatory, the Partin

reference would need to disclose each and every limitation of the claimed invention. Looking only at claim 1, this standard is plainly not met.

Partin discloses a fiber optic which has an immobilized antibody and a labeled antigen on its surface. Since the labeled antigen is displaced by analyte, this can be equated with the first surface in the present claims. When analyte of interest is present, the second step of Applicants method, i.e., "exposing the first surface to a sample comprising the analyte of interest, whereby the analyte of interest specifically displaces the displaceable moiety from the first surface" occurs. That, however, is the end of the similarity. Partin does not "caus[e] the displaceable moiety displaced from the first surface to contact a second surface bearing a capture moiety which specifically binds to the displaceable moiety." In fact, the displaced labeled antigens apparently just fall off to be sucked up in the vacuum system. Accordingly, there is no "capture [of] the displaceable moiety on the second surface" and no generation of a species at the second surface "capable of producing a detectable signal". There is also no disclosure of "treating the species capable of producing a detectable signal to generate said signal." Thus, Partin manifestly does not teach each and every element of the claimed invention and cannot be deemed anticipatory.

The Examiner has rejected claims 6 and 22 as obvious over Schramm or Partin. Applicants assume that the Examiner intended to include a Badley et al. reference in the statement of the rejection. However, since there are multiple Badley et al. references of record, it is not clear which reference the Examiner is relying on. To the extent that it may be inferred that the Badley reference cited is US Patent No. 6,294,391, which was enclosed with the Office Action, Applicants point out that the Badley patent and this application are commonly assigned and were the time the invention was made, owned by, or subject to an obligation of assignment to, the same entity. Thus, Badley '391 is not available as art for purposes of a § 103 rejection. Furthermore, this rejection assumes that the basic arguments concerning Schramm and Partin are correct. For all of these reasons, this rejection should be withdrawn as well.

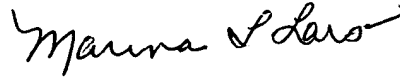
The Examiner has rejected claim 5 as obvious over Schramm or Partin. In the description of the rejection, however, the Examiner refers to Presta et al. Applicants assumes that this is US Patent No. 6,025, 166 which was provided with the Office Action. This rejection

assumes that the basic arguments concerning Schramm and Partin are correct. Since this is not the case, this rejection should be withdrawn as well.

The Examiner rejected claim 12 as obvious over Schramm or Partin in view of Alcock. The deficiencies of the base references have been previously discussed. Thus as a first matter, Applicants submit that whatever combination may be suggested by the references, it is not the invention as presently claimed. Looking specifically at claim 12, the Examiner states that Schramm and Partin differ from the invention "in failing to disclose that the capture of the displaceable moiety modulates an electrochemical property of the capture moiety, which modulation comprises a detectable signal." The Examiner says that Alcock makes up this deficiency, but does not point out any specific section of the Alcock teaching. Applicants point out that while Alcock does describe electrochemical detection, through the generation or suppression of generation of an electrochemically detectible species as one of several options, there is no specific teaching that there is capture contemplated in the detection zone of a competitive assay. For example, in Example 3, the device described appears to be a sandwich assay construction, while at Col. 15, where a displacement assay is described, the only thing mentioned at the detection site is glucose, the substrate for the displaced enzyme-conjugate. This being the case, the Examiner seems to have selected words from the Alcock reference using the present claims as a guide, rather than reviewing what the combined references would actually have suggested to a person skilled in the art. Furthermore, the Examiner has not indicated how a liquid system could fairly be combined with the Partin reference which relates to gas phase detection of materials.

In view of the foregoing arguments, Applicants submit that all claims are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Marina T. Larson". The signature is fluid and cursive, with a long horizontal stroke at the end.

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